Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA.30S)
Rockville, MD 20852

May 7, 2004

Dear Sirs/Madame:

As representatives of the patient and consumer communities, we believe that the outcomes and comparative effectiveness studies required by Section 1013 of the Medicare Prescription Drug. Improvement, and Modernization Act of 2003, have the potential to improve the quality of care and maximize patient outcomes. However, given the focus on prescription drugs as the first priority, we are concerned that this research will be used to determine patients' access to medicines solely based on which prescription medicine is least expensive, as opposed to which would be most effective. Consequently, we urge that the following comments be used as guidelines to help ensure that government-sponsored health outcomes research (including research on comparative and cost-effectiveness of medicines) meets patients' needs and supports the need for continued strides in overall medical care:

- Research should be conducted in the context of overall health care quality improvement. It should occur as part of a broad agenda to improve health care quality and patient outcomes across the health care system. Efforts focused on cost-containment for one service or product alone (e.g., medications) often shift costs from one medical service to another without improving patient outcomes.

- Government priorities for research should focus on diseases that impose high clinical and economic burdens on patients and society, rather than being limited to high cost medical interventions.

- Health outcomes research should consider the full range of health care interventions, and evaluate total health care costs or savings over the length of a treatment horizon, including patient costs for commuting to health care facilities in rural areas, not just the costs of specific treatments.

- Patients have unique medical needs that are often not reflected in population-level research. Government health outcomes research should be just one tool to inform doctor-patient decision-making. Clinical judgment and patient choice, within the bounds of acceptable medical practice, must always be the overriding force in decisions about individual care.

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- Research should also evaluate the needs of patient sub-populations, who often respond differently to medicines and need a variety of treatment options/combinations for the best outcome.

- Research findings should support patient access to appropriate health technologies, and not be used as a tool to restrict or delay access to treatment choices. A new, "incremental" advance in medicine can appear similar to others in the same class. But, in fact, it can provide important and cost-saving benefits such as fewer side effects or improved compliance.

- Government decisions about the focus and design of research programs should be made through open, transparent procedures with the involvement of stakeholders, including patients, family members, providers and medical researchers. Findings should be communicated in an understandable way to stakeholders, including the range of peer-reviewed results on all treatment options.

- Research should evaluate both the direct benefits and the indirect benefits of health care interventions, including quality of life, patient functionality and economic productivity.

- Government is well positioned to help design and support research programs. Researchers can evaluate the benefits and risks of medical innovations, evaluating prospectively the value of different types of medical evidence in different clinical settings, and identifying the best methods to rapidly and broadly disseminate knowledge of medical advances. Standards for evidence should be consistent, transparent, and objective. Additionally, standards should be established independently of potentially conflicted parties, including payers.

- Caution must be exercised in the use of this research. It is clear that Congress intended this research to primarily inform the clinical decision-making process rather than the reimbursement process. Payers may have a conflict between reducing costs and maximizing quality and patient outcomes. Reimbursement decisions should be driven by quality and outcomes, not by cost.

- Within a therapeutic class there should be a minimum of three medications before prior authorization is allowed in order to maintain doctor-patient choice. A minimum of two medications must be available without restriction.

- Certain types of medicines should never be subjected to prior authorization restrictions due to the complexity of the condition being treated and the higher potential for adverse events from medication switches. Medications that should be exempt from prior authorization include those to treat, epilepsy, lupus, HIV, cancer, heart disease, mental illness, and asthma.

- Restrictions on access to care must include a fair and consistent appeals process readily accessible to patients and providers.

Thank you for your consideration. Access to medicines is a preeminent issue to both patients and consumers. We will be closely monitoring this matter.

Sincerely,

The American Autoimmune and Related Disease Association
The Asthma and Allergy Foundation of America
The Lupus Foundation of America
The National Alliance for the Mentally Ill
The National Alliance for Caregiving
The National Coalition for Women with Heart Disease
The National Grange
The National Mental Health Association
The National Medical Association
The National Osteoporosis Foundation
The National Association for Continence
Men's Health Network
RetireSafe.org
Spina Bifida Association